REMARKS/ARGUMENTS

With respect to the objection to claims 44 – 52, 58, 60 – 66, 72, 74 and 79, in paragraph 2 of the Office Action, as an initial matter, claim 79 is believed to be erroneously included in this group as it depends from allowed claim 75 and is not directed to a kit *per se*. With the cancellation of claims 47, 50, 63, 66, 72, and 74, and amendment of all of the independent claims in this group (claims 44 and 60), rejection of the remaining claims in this group is respectfully traversed. Claims 44 and 60 have each been amended to call for the peptides of the peptide panel to bind T cells indicative of infection with the mycobacterium in humans. The suggestion of the Examiner in section 2 of the Office Action that there is additional .need for positive inclusion in the same claims of a component or element for detection overlooks that kits according to claim 44 may be used for *in vivo* diagnostic tests as described in the description at line 12 on page 8 to line 2 on page 9. This is certainly the case for kits according to claim 60 comprising one or more polynucleotides which can express in human cells a peptide panel. Such *in vivo* diagnostic tests evidently do not require any detection component. For example, peptides may be administered epidermally in a similar manner as antigen for a conventional skin test for TB. Recognition of the peptide by T cell:; may then be assessed by visual examination of the skin around the site of peptide administration (note in particular the paragraph bridging pages 8 and 9 of the description). For *in vitro* diagnosis according to the invention, a means to detect recognition of peptide by T cells is essential, but might, of course, be obtained separate from a peptide panel in kit form. Hence, kit claim. 44 specifies such a means as optional. No essential element has been omitted.

With respect to the objection to claims 34, 49, 58, 65, 72 and 79, in paragraph 2 of the Office Action, with the cancellation of claim 72, and amendment of all of the remaining in this group, rejection of the remaining claims in this group is respectfully traversed. In each of claims 34, 49, 58, 65 and 79, reference in the alternative to deletions at the N-terminus or C-terminus has been replaced by reference to have been amended to call for end terminal deletions, thereby obviating the objection.

Referring to paragraph 3 of the Office Action, the rejection of claims 32 –35, 48 – 50, 56 – 59, 63 – 66 and 77 – 80, in as not being enabled is respectfully

traversed, As an initial matter, claim 34, 58 and 79 are believed to be erroneously included in this group as they depend from allowed claims, and are not believed to incorporate any matter indicated to be objectionable. Similarly, claims 49 and 65 are believed to be erroneously included in this group as they depend from claims that are not rejected on lack of enablement, and are not believed to incorporate any matter indicated to be objectionable. Claims 32, 35, 50, 56, 59, 63, 66, 77 and 80 have been cancelled, and the remaining claims in this group have each been amended to refer to peptide analogues having at least 90% homology to an entire peptide.

The rejection of the remaining claims in this group is respectfully traversed. The peptides of concern in claim 27 are T cell-activating peptides, more particularly peptides presenting $CD4^{+}T$ cell epitopes. As stated at M.P.E.P. 2164.01(a), There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. The examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. 858 F.2d at 737, 740, 8 USPQ2d at 1404, 1407. A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual

determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement). In Wands, the court noted that there was no disagreement as to the facts, but merely a disagreement as to the interpretation of the data and the conclusion to be made from the facts. In re Wands, 858 F.2d at 736-40, 8 USPQ2d at 1403-07. The Court held that the specification was enabling with respect to the claims at issue and found that "there was considerable direction and guidance" in the specification; there was "a high level of skill in the art at the time the application was filed;" and "all of the methods needed to practice the invention were well known." 858 F.2d at 740, 8 USPQ2d at 1406. After considering all the factors related to the enablement issue, the court concluded that "it would not require undue experimentation to obtain antibodies needed to practice the claimed invention." Id., 8 USPQ2d at 1407.

In the instant case, it is respectfully submitted that at the time of filing the application, it would have been a simple matter for others with knowledge of T cell immunology to obtain analogues of such peptides which retain the ability to be recognised by T cells of a T cell population which recognise the parent peptide (the functional test for a peptide analogue specified in the claims). By the filing date, much was known about how T cell epitopes are recognised by T cell receptors in conjunction with HLA molecules and hence a person with knowledge of T cell immunology in seeking to identify analogues of peptides specified in claim 1 certainly would not be operating without any guidance.

With the cancellation of claims 67 – 74, no comment is made with respect to the rejection in paragraph 4 of the Office Action.

In view of the amendments and foregoing remarks it is believed that the application is now in condition for allowance and respectfully solicits a Notice of Allowance.

The Commissioner is hereby authorized to charge payment of any fees required associated with this communication or credit any overpayment to Deposit

Account No. 50-0337. If an extension of time is required, please consider this a petition therefor and charge any additional fees which may be required to Deposit Account No. 50-0337. A duplicate copy of this page is enclosed.

Respectfully submitted,

Robert Berliner
Registration No. 20,121

Tel.: (213) 892-9200
Fax: (213) 680-4518